promoter sequence operably linked to a heterologous polynucleotide sequence encoding a MYB polypeptide, wherein the polynucleotide comprises a sequence at least 80% identical to SEQ ID NO:1.

N. A recombinant expression cassette comprising a promoter sequence operably linked to a heterologous polynucleotide sequence encoding a MYB polypeptide, wherein the polynucleotide comprises a sequence at least 80% identical to SEQ ID NO:1.

REMARKS

Claims 1, 3, 5, 7-11, 13, 15, 17-20 are pending in the application. Claims 1 and 11 were amended. These amendments add no new matter. Support for these amendments can be found, e.g., in the claims as filed and in the specification on page 2, lines 28-34 and on page 5, lines 10-19. Claims 2 and 12 were canceled without prejudice to subsequent revival. Appendix A provides the version with markings to show changes made. All pending claims are provided in Appendix B for the Examiner's convenience.

Rejection under 35 U.S.C. § 112

Claims 1-3, 5, 7-13, 15, and 17-20 are rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement as the specification allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope. The Examiner concedes that the specification is enabling for claims limited to an isolated *Gossypium hirsutum* cDNA ghMYB1 of SEQ ID NO:1 encoding SEQ ID NO:2 and tobacco transformation therewith, but states that the function of an isolated nucleic acid other than SEQ ID NO:1 cannot be determined on the basis of its nucleotide sequence alone and the unpredictability of altering the phenotype of a plant by transforming it with an isolated

nucleic acid that has sequence similarity to a MYB polypeptide or that has at least about 30 nucleotides of a MYB polynucleotide other than SEQ ID NO:1.

To the extent that the rejection applies to the claims as amended, Applicant respectfully traverses. Applicant now claims a method of modulating transcription in a plant comprising introducing into a plant a recombinant expression cassette comprising a promoter sequence operably linked to a polynucleotides sequence encoding a MYB polypeptide, wherein the polynucleotide comprises a sequence *at least 80% identical* to SEQ ID NO:1. The present specification teaches the highly conserved structural similarities between the claimed MYB transcription factors and other known plant MYB transcription factors from different species. The specification also teaches a method of determining whether a plant was transformed with a MYB nucleic acid by determining fiber qualities. Accordingly, the teachings of the specification, in combination with the level of skill in the art, enable the skilled practitioner to identify MYB nucleic acids of the present invention and to express them in transgenic plants.

A. MYB transcription factors share significant structural similarities

The present specification teaches how to use structural data to determine whether a putative MYB transcription factor is, in fact, a MYB transcription factor used in the methods and compositions of the present invention. As described in the present specification, cDNA clones encoding cotton MYB-domain genes were isolated from cotton ovules and were characterized. Structural comparisons were made to determine whether the clones were, in fact, MYB transcription factors. Structural similarities among the MYB transcription factors used in the methods and compositions of the present invention and other already known plant MYB transcription factors include a typical R2/R3 repeat, a tryptophan hydrophobic core and conserved DNA base-contacting residues that function in recognition specificity (*see* specification: page 4, lines 14-24 and page 25, lines 4-7). These conserved domains are well known in the art and signify to the skilled practitioner that a sequence encodes a MYB transcription factor. On page 4 of the specification, Applicant explains that although various modification

may be made to MYB polypeptide sequences without affecting their function, the MYB encoding sequences must contain the conserved functional domains easily identifiable by those skilled in the art as MYB domains.

Applicant teaches in the specification how to compare MYB encoding sequences from different species in order to determine if a candidate nucleic acid is a cotton MYB transcription factor. For example, on page 22 of the specification, Applicant explains that structural similarities were determined by comparing the primary amino acid sequence of the MYB sequences by means of multiple sequence alignment performed separately for the conserved DNA binding domains and the C-terminal domains of the sequences. PileUp software was used for this purpose. Additionally, on page 26 of the specification, Applicant explains that a dendogram of MYB encoding sequences can be generated in order to determine the structural similarities. Accordingly, the specification teaches how to determine if a putative sequence contains the conserved domains of MYB nucleic acids and therefore, encodes a MYB transcription factor.

B. MYB transcription factors of the present invention, when expressed in plants, modulate fiber properties

In the present application, Applicant teaches how to produce transgenic plants transformed with MYB nucleic acids. On page 18 of the specification, techniques for introducing DNA constructs comprising MYB nucleic acids into the genome of a desired plant host are described. On page 20, Applicant teaches several parameters that can be measured to compare the properties or quality of fibers produced from transgenic plants transformed with MYB nucleic acids and the quality of fibers produced from native plants. These qualities include fiber length, fiber strength and fineness of fibers. If a plant transformed with a putative MYB nucleic acid does not produce plants with altered fiber quality, the skilled practitioner would understand that the putative transcription factor is not a MYB transcription factor of the present invention. If, however, a plant transformed with a putative MYB nucleic acid does produce plants with

altered fiber quality, the skilled practitioner would understand that the putative transcription factor is, in a fact, a MYB nucleic acid of the present invention.

C. Identification of MYB genes other than SEQ ID NO:1 does not require undue experimentation

After reviewing the pending claims, the Examiner should find that this invention does not require undue experimentation. As identified in the Patent Office and the Federal Circuit, whether undue experimentation is required by one skilled in the art to practice the invention is determined by considering factors such as the amount of guidance presented, the state of the prior art, and the presence of working examples. *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int. 1985); *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). As described in *Wands*, a "considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should precede." *Wands*, 8 USPQ2d at 1404 (quoting *In re Jackson*, 217 USPQ 804 (Bd. Pat. App. & Int. 1982).

The claims now specify that the MYB gene must be at least 80% identical to SEQ ID NO:1. This requirement of at least 80% identity makes the identification of claimed nucleic acids easily accomplished by one of skill in the art. Sequence comparisons for the identification of nucleic acids are well known to those of skill in molecular biology. The present application teaches which positions are conserved and therefore which positions are critical for the function of the MYB polypeptides. The present application also teaches how to perform functional assays to determine the function of the claimed nucleic acids, e.g., plant transformation and fiber analysis. Accordingly, the present application teaches how to distinguish a sequence encoding a MYB transcription factor from a sequence that may possess some similarity to the MYB nucleic acid but does not, in fact, encode a polypeptide with MYB function.

The test of enablement is whether one reasonably skilled in the art can make the invention from the disclosure without undue experimentation. The claims as

amended recite structural characteristics, e.g., at least 80% sequence identity. The present specification teaches the conserved motifs. The specification also teaches how to functionally determine whether a putative MYB nucleic acid is a nucleic acid of the invention. Accordingly, after reading the present application, one of skill in the art would know how to structurally characterize a sequence and test a sequence believed to be a MYB nucleic acid sequence of the present invention.

The specification, combined with the state of the prior art, thus teach the identification and characterization of MYB transcription factors at least 80% identical to SEQ ID NO:1. The methods of the present invention are therefore enabled as required by the Patent and Trademark Office guidelines. Applicants respectfully request that the rejection be withdrawn.

Rejections under 35 U.S.C. § 102(b)

Claims 1, 2, 10-12 and 18-19 are rejected as allegedly being anticipated by Quattrocchio *et al.* (1998, *The Plant Journal* 13(4):475-488) and by Wada *et al.* (1997, Science 277:1113-1116). The Examiner alleges that Quattrocchio *et al.* teaches the MYB transcription factor, an2, which is greater than 30 nucleotides and Wada *et al.* teaches CAPRICE which encodes a polypeptide with a MYB-like domain and is greater than 30 nucleotides in length. To the extent that the rejection applies to the claims as amended, Applicant respectfully traverses.

As the Examiner is well aware, for a rejection under § 102(b) to be properly founded, a single prior art reference must disclose, either expressly or inherently, each and every element of the claimed invention. *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Verdegaal Bros. V. Union Oil Co. Of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). In *Scripps Clinic & Research Found. v. Genetech, Inc.*, 18 USPQ2d 1001 (Fed. Cir. 1991), the Federal Circuit held that:

> Invalidity for anticipation requires that all of the elements and limitations of the claim are found with a single prior art reference. . . .There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Id.* at 1010.

Anticipation can be found, therefore, only when a cited reference discloses all of the elements, features or limitations of the presently claimed invention.

The rejection cites Quattrocchio *et al.* and Wada *et al* as the basis for the § 102(b) rejection. Applicants respectfully submit that neither reference discloses every element of the presently claimed invention and, thus, neither reference can form the basis for a § 102(b) rejection. Namely, the cited references do not expressly or inherently disclose a method of modulating transcription in a plant using a polynucleotide comprising a sequence at least 80% identical to SEQ ID NO:1. The cites references also do not expressly or inherently disclose a recombinant expression cassette comprising a polynucleotide comprising a sequence at least 80% identical to SEQ ID NO:1.

A. The cited references fail to explicitly or inherently disclose methods of using a sequence at least 80% identical to SEQ ID NO:1 or expression cassettes comprising a sequence at least 80% identical to SEQ ID NO:1

The Quattrocchio *et al.* reference reports the functional analysis of two regulatory pigmentation genes, an2 and jaf13. The Quattrocchio *et al.* reference also refers to the isolation of the an2 gene and the determination that an2 encodes a MYB domain protein. The Wada *et al.* reference describes a CAPRICE gene which encodes a protein with a MYB-like DNA binding domain. The Examiner has provided no evidence that the an2 gene disclosed in Quattrocchio *et al.* or the CAPRICE gene disclosed in Wada *et al.* share at least 80% identity to SEQ ID NO:1. In the absence of such a showing, the Examiner must withdraw the rejection.

Accordingly, Applicant respectfully requests that the rejection be withdrawn.

Rejections under 35 U.S.C. § 102(f)

Claims 1-3, 7-13, 15, and 17-20 are rejected under 35 U.S.C. § 102(f) because the Examiner alleges that the applicant did not invent the claimed subject matter. The Examiner uses the Loguercio *et al.* reference and the NCBI database to allege that the Applicant is not the inventor of the claimed subject matter. Applicant respectfully traverses.

A. The Loguercio *et al.* reference

In the present Office Action, the Examiner states applicant did not invent the claimed subject matter because the Loguercio *et al.* reference lists two authors in addition to the applicant. The Examiner believes those additional authors to be co-inventors.

According to the MPEP, when the applicant is one of the co-authors of a publication cited against her application, the applicant may overcome the rejection by filing a specific declaration under 37 CFR §1.132 indicating that the applicant is the sole inventor and the others were merely working under her direction. MPEP 715.01(c), *In re Katz,* 687 F.2d 450. With this amendment, Applicant submits a Declaration Under 37 C.F.R. §1.132 stating that applicant is the inventor of the claims under examination to the extent that the subject matter disclosed and claimed is also disclosed in Loguercio *et al., Mol. Gen. Genet* (1999) 261:660-671. Applicant further declares that although L.L. Loguercio and J.-Q Zhang co-authored the publication, they are not co-inventors of the subject matter described therein. Accordingly, Applicant respectfully requests that the rejection be withdrawn.

B. The NCBI database disclosure

In the present Office Action, the Examiner states applicant did not invent the claimed subject matter because the NCBI database discloses SEQ ID NO:1 (Accession number L04497) which was deposited by Wilkins and Lu, C-C. Applicant respectfully traverses.

The NCBI database discloses SEQ ID NO:1, however, the NCBI database does not disclose that SEQ ID NO:1 encodes a MYB transcription factor capable of modulating transcription in a plant. In contrast, the present application claims methods of modulating transcription in a plant, the method comprising introducing into a plant a recombinant expression cassette comprising a promoter sequence operably linked to a polynucleotide comprising a sequence with at least 80% identity to SEQ ID NO:1. Accordingly, the NCBI database does not disclose the invention claimed in the present application. Applicant therefore respectfully requests that the rejection be withdrawn.

Rejections under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1-3, 5, 9-12 and 18-19 under 35 U.S.C. 103(a) as allegedly being obvious over Wada *et al.* in view of Wilkins *et al.* To the extent that the rejection applies to the claims as amended, Applicant respectfully traverses the rejection. M.P.E.P. § 2143 states the following:

> "[t]o establish a *prima facie* case of obviousness, *three* basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)."

All three elements set forth above must be present in order to establish a *prima facie* case of obviousness. Applicant asserts that a *prima facie* case of obviousness has not been established for the following reasons: 1) there is no suggestion or motivation to modify the references; 2) there is no reasonable expectation of success; and 3) the cited art references do not teach or suggest all the claim limitations.

There is no Suggestion or Motivation to Modify the References

Applicant submits that there is simply no motivation or suggestion provided in the cited references to use the sequence disclosed in Accession number L04497 either in the methods of the present invention or in an expression cassette of the present invention.

As the Examiner is aware, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

As discussed above, Wada *et al.* teaches a mutated gene, CAPRICE, which encodes a protein with a MYB-like DNA binding domain typical of transcription factors involved in animal and plant development. Functionally, Wada *et al.* hypothesize that CPC is involved in the developmental pathway of root hair formation.

As also discussed above, the NCBI database discloses SEQ ID NO:1 and refers to SEQ ID NO:1 as a cotton DNA binding domain mRNA or a MYB DNA-binding domain repeat signature 1.

In contrast, the present applicant teaches using SEQ ID NO:1 or a sequence at least 80% identical to SEQ ID NO:1 to modulate transcription in plants. Neither the Wada *et al.* reference or the NCBI publication teach or suggest that SEQ ID NO:1 can be used to modulate transcription in plants. Applicant submits that the NCBI disclosure coupled with the knowledge that sequences encoding MYB polypeptides regulate transcription does not teach or suggest to someone of skill in the art that SEQ ID NO:1 expressed in a plant would modulate transcription in that plant or that SEQ ID NO:1 should be linked to a promoter in an expression cassette.

Accordingly, there is no suggestion or motivation in either the Wada *et al.* reference or NCBI publication, separately, or together, to use SEQ ID NO:1 in the methods or compositions of the present invention.

Applicants respectfully request that the Examiner withdraw the rejection of claims 1-3, 5, 9-12 and 18-19 over Wada *et al.* in view NCBI accession number L04497.

There is No Reasonable Expectation of Success

In addition, in view of the cited publications, one of skill in the art would have had no reasonable expectation of success that SEQ ID NO:1 expressed in plants would modulate transcription in those plants, "Both the suggestion and the expectation of success must be found in the prior art, not the Applicants' disclosure." *In re Dow Chem. Co.*, 5 U.S.P.Q.2d 1529, 1532 (Fed. Cir. 1988).

Applicant asserts that there is no teaching or suggestion in the cited art to modify the teaching therein to arrive at the presently claimed invention. Both references are silent as to the use of SEQ ID NO:1 to modulate plant transcription. Furthermore, the Examiner provides no reasoning or evidence to demonstrate that the claimed sequences could be expected to have the phenotypic effect noted here. A skilled practitioner, in view of Wada *et al.* and the NCBI publication, would have no expectation of successfully modulating transcription in a plant by expressing the claimed sequences. Accordingly, Applicant again respectfully requests that the Examiner withdraw the rejection of claims 1-3, 5, 9-12 and 18-19 over Wada *et al.* in view NCBI accession number L04497.

The Cited Art References Do Not Teach All Limitations of the Claims

The prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970). Applicants assert that the prior art references do not teach or suggest all the limitations of the claims and therefore, the obviousness rejection is untenable.

Applicants claim a novel method of modulating transcription in a plant. Under *In re Wilson supra, a prima facie* case of obviousness has not been established as each of the limitations of the claims is not taught or suggested in the cited art references. Neither publication teaches or suggests a method of modulating transcription in a plant using a sequence at least 80% identical to SEQ ID NO:1.

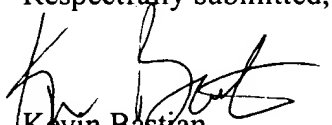
As the prior art references do not teach every element of the claimed invention, Applicant once again respectfully requests that the Examiner withdraw the rejection of claims 1-3, 5, 9-12 and 18-19 over Wada *et al.* in view NCBI accession number L04497.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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APPENDIX A
VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. A method of modulating transcription in a plant, the method comprising introducing into the plant a recombinant expression cassette comprising a promoter sequence operably linked to a heterologous polynucleotide sequence encoding a MYB polypeptide[.], wherein the polynucleotide comprises a sequence at least 80% identical to SEQ ID NO:1.

11. A recombinant expression cassette comprising a promoter sequence operably linked to a heterologous polynucleotide sequence encoding a MYB polypeptide[.], wherein the polynucleotide comprises a sequence at least 80% identical to SEQ ID NO:1.